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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,349	05/15/2001	Daniel Plaksin	87534-2800	2778

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,349

Applicant(s)

PLAKSIN, DANIEL

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/18/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 11-18, 20, 37-39 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-10, 19, 34-36, 40 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

Claims 1-20 and 34-47 are pending in the application.

Claims 21-33 have been cancelled in the 5/15/03 Amendment.

Claims 5-8, 11-18, 20, 37-39 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Applicants state at page 6 of the REMARKS that the claims that read on the species are claims 1-3, 9-10, 13-16 and 18-20. However, the claims that read on the elected species are claims 1-4, 9-10, 19, 34-36 and 40.

Claims 1-4, 9-10, 19, 34-36, 40 and 45-47 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling for the reasons advanced in the last Office action.

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Response to Arguments

In view of the amendments to claim 1 the rejection in the last Office action no longer applies.

Claims 1 and 47, as amended, do not provide a detail description of the residues that would be included by the proviso "other than Gly". The only specific description for the other residue is Lys. However, the proviso encompasses all natural, unnatural, charge or uncharged amino acid other than Gly. The single residue described in the specification is therefore insufficient support for the proviso, as recited.

Claim 34, as amended, reciting a polypeptide that is ***predominantly*** monomeric is not supported in the as-filed specification. The specification does not provide a definition, percent or amount of the monomer of a polypeptide that is considered predominant in a sequence.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9-10, 19, 34-36, 40 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

Response to Arguments

A. In view of the amendment to claim 1, the rejection under this paragraph (A) in the last Office no longer applies. However, applicant's REMARKS as to the Figure 1 and Seq. ID. No. 2 reciting Lys at the 45th position is unclear. Even in the presence of a 35a residue as shown in the attached Reiter article, still residue 44 will be considered the 44th position with said Lys. Thus, applicant's argument is confusing.

B. The argument as to the used of "unique" term is moot with the cancellation of said term. However, with respect to Claims 3 and 35 as being confusing with respect to the used of the various compounds e.g., polynucleotides, vectors and etc. is maintained. Applicant has not addressed this rejection hence it is believed he is acquiescing therewith.

C. Applicant argues that production of polypeptide in a specific host only limits the possibilities and further

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defines the polypeptide described in claims 3 and 34, as a skilled in the art would understand.

In response, applicant's arguments as to the limitation of the possibilities are unclear as to what exactly are these possibilities. Applicant's amendment to claim 4 renders the claim more confusing.

D. Applicant argues that the residues 100C is according to the Kabat nomenclature.

In reply, there is nothing the specification that alludes to the Kabat nomenclature.

E. Applicants argue that in claim 34, the term "substantially" has been replaced by predominantly.

Applicants point out support for said term at page 12, line 24; page 15, line 24 and page 25, line 11. A review of the cited section does not reveal said term. Furthermore, predominantly is also indefinite, especially in the absence of positive support in the specification.

F. Claim 35 is but claim 19, as amended. Claim 19, which depends on claim 3, has the same limitation as claim 35, which is dependent on claim 19. Claim 19 as stated ultimately depends on claim 3.

G. New claim 47 is a duplicate of claim 19. The same ingredients in each instances is being claimed. The manner

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by which the polypeptide of claim 19 is obtained does not have a bearing on a composition that contains the same components i.e., the polypeptide and carrier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Claims 1-4, 9-10, 19, 34-36, 40 and 45-47 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for reasons set forth in the last Office action.

Response to Arguments

Applicant admits that the Reiter reference was indeed a scientific description of the invention that was invented solely by the present inventor. But argue that the other authors were added to reflect their general scientific contribution and not their contribution to the inventiveness of the subject matter. The term "we" on page 26 of the specification was used because the technical experiments were performed with the aid of the other technicians and services who did not contribute to the inventive step of the invention and are therefore not inventors

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as defined by the MPEP. Applicant submits a certified copy of Israeli priority application 127127, establishing the priority date as Nov. 11, 1998.

In response, the priority document is not on file.

Furthermore, there is no evidence on the record, e.g., in the form of a declaration, that the other authors are not inventors.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

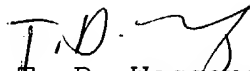
This application contains claims drawn to an invention nonelected with traverse in Paper No. 5-8, 11-18, 20, 37-39 and 41-44. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 15, 2004